



# Gene Test Predicts DCIS Recurrence Risk

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*A 12-gene test for breast cancer recurrence after ductal carcinoma in situ (DCIS) distinguished high- and intermediate- risk patients from those with a low risk*

Eileen Rakovitch, MD

A 12-gene test for breast cancer recurrence after ductal carcinoma in situ (DCIS) distinguished high- and intermediate- risk patients from those with a low risk, according to a study reported at the 2014 San Antonio Breast Cancer Symposium.<sup>1</sup>

Patients with a high or intermediate DCIS recurrence score had a 2- to 3-fold higher 10-year recurrence rate as compared with the low-risk group. The test identified patients with an increased risk of both invasive and DCIS recurrence.

“Our results show that the DCIS Score is predictive of local recurrence in a general population of women with DCIS,” said Eileen Rakovitch, MD, the LC Campbell Chair in Breast Cancer Research at the Odette Cancer Centre at Sunnybrook Health Sciences Centre in Toronto.

“This the first biomarker assay to provide individualized estimates of the risk of local recurrence in women treated by breast-conserving surgery alone,” said Rakovitch. “This can help clinicians and patients make more informed decisions about their risks and potential benefits of treatment.”

DCIS accounts for 30% of all newly diagnosed breast cancers. Though not an invasive cancer, DCIS confers a risk of invasive recurrence, prompting recommendations for treatment.

In most cases, patients with DCIS undergo breast-conserving surgery and adjuvant radiation therapy. Breast-conserving surgery alone is an option for patients with a low risk of local recurrence, said Rakovitch.

Clinical and pathological features of DCIS do not reliably predict recurrence risk, leading to overtreatment of low-risk patients and undertreatment of high-risk patients. Biomarkers to risk-stratify patients would help prevent inappropriate treatment, Rakovitch noted.

Investigators in the Eastern Cooperative Oncology Group E5194 Study evaluated the *Oncotype DX* DCIS Score in patients undergoing breast-conserving surgery alone. The results showed the DCIS Score did predict recurrence risk.<sup>2</sup> Whether the results applied to the general population of patients with DCIS remained unclear.

Rakovitch and colleagues performed a population-based validation study of the DCIS Score. The score is derived from the gene expression pattern associated with an individual patient’s DCIS. A score of <39 predicts a low risk of recurrence, 39 to 54 predicts intermediate risk, and <sup>3</sup>55 predicts a high risk of local recurrence.

The validation study involved a population-based cohort with diagnoses of pure DCIS from 1994 to 2003. The patients underwent breast-conserving surgery alone and achieved negative margins in each case.

Data analysis included 571 patients with a median follow-up of 9.4 years. The DCIS test results predicted a low risk of recurrence in 355 patients, intermediate risk in 95 patients, and high risk in 121 patients. Follow-up for the cohort showed a 10-year recurrence incidence of 12.7% in patients with low-risk DCIS scores, 33.0% in patients with an intermediate-risk score, and 27.8% in patients with a high-risk score ( $P < .001$ ).



Rakovitch and colleagues analyzed the data associated with invasive recurrence and DCIS recurrence. The results showed a 10-year risk of invasive local recurrence of 8.0% for low-risk patients, 20.9% for intermediate-risk patients, and 15.5% for high-risk patients ( $P = .03$ ). Rates of DCIS local recurrence at 10 years were 5.4% for low-risk patients, 14.1% for intermediate-risk patients, and 13.7% for high-risk patients ( $P = .002$ ).

During the discussion that followed her presentation, Rakovitch acknowledged the similarity of results in the intermediate and high-risk groups. Combining the two into a single risk score is an issue for the manufacturer, Genomic Health, to decide in taking the test forward, she said.

### References

1. Rakovitch E, Nofech-Mozes S, Hanna W, et al. A population-based validation study of the DCIS Score predicting recurrence risk in individuals treated by breast-conserving surgery. Paper presented at: San Antonio Breast Cancer Symposium; December 9-13, 2014; San Antonio, TX. Abstract S5-04.
2. Solin LJ, Gray R, Baehner FL, et al. A multigene expression assay to predict local recurrence risk for ductal carcinoma in situ of the breast [published online May 2, 2013]. *J Natl Cancer Inst*. 2013;105(10):701-710.

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